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10/551,789	07/05/2006	Michael Thomas Clandinin	PAT 978W-2	3396

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,789	CLANDININ, MICHAEL THOMAS	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,17 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,17 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/08, 3/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/CA04/00375, filed March 12, 2004, which claims priority to US application 10/404095, now US patent 6998392, filed April 2, 2003. Claims 2-13, 17, and 19-25 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted July 20, 2007 is acknowledged wherein claims 2-13, 17, and 19-25 are amended and claims 1, 14-16, 18, and 26, and 27 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an inflammatory disease does not reasonably provide enablement for preventing said toxicity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a therapeutic method for treatment or prevention of disease. In the absence of an explicit definition in Applicant's specification, the claims are given their broadest reasonable interpretation. See MPEP 2111. Merriam-Webster's Collegiate Dictionary (reference included with PTO-892) defines "prevent" as meaning, "to deprive of power or hope of acting or succeeding," or "to keep from happening or existing." This definition is taken as representing the ordinary usage of the term "preventative". In order to deprive something of power or hope of acting or succeeding, the preventative agent must be completely effective. "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Merely slowing the onset of disease or making the disease less likely would still leave it with "power or hope of acting or succeeding," and thus not qualify as prevention.

The state of the prior art: Many diseases exist that involve inflammation to some extent. A vast number of different compounds are found to influence the process of inflammation, and are useful in treating inflammation in theses conditions. However, these treatments do not qualify as preventative treatments in the sense described above under the heading "Nature of the invention"

More generally, prevention of any disorder in the sense being used herein is not a recognized clinical outcome in the art, as no treatment is perfectly effective.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms? For example, will a metastatic cancer eventually adapt to overcome treatments directed to preventing it from metastasizing into the bone? Or will a case of osteoporosis or rheumatoid arthritis ultimately progress to a point where symptoms develop regardless of which therapy is administered.

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease

safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer.

The Breadth of the claims: In the absence of an explicit definition in Applicant's specification, "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Any therapy which merely reduces the number or severity of symptoms, or which is effective for a period shorter than the subject's remaining lifespan, is considered to be ineffective at preventing a disorder.

The amount of direction or guidance presented: The claimed gangliosides are shown to attenuate inflammatory mediators in rat intestine. (p. 31 example 4 of the specification) However, no guidance is given in the specification suggesting any reason to believe that administration of a ganglioside composition can fully prevent the later occurrence of any and all inflammatory diseases.

The presence or absence of working examples: No working examples are provided for treatment or prevention of inflammatory disease.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. In particular, one skilled in the art, in order to practice the invention for prevention of disease, would need to know whether the preventative effect remains potent over the long term.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or monkeys, or a human clinical trial. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering the claimed compounds for a period of years to a suitable subject population is an undue amount of experimentation needed in order to practice the full range of the claimed invention. As prevention in the full sense is an extremely high bar for any clinical outcome, there is no reason to believe that the therapy would be successful, and any actual success would be a surprising and unpredictable result.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the nature of the invention and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of inflammatory disease.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 2-3, 8-13, 17, and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al. (US pre-grant publication 2004/0047856, cited in PTO-892)

Williams et al. discloses a composition comprising colostrum, hyperimmune milk, and a ganglioside. (p. 2 paragraphs 0020-0021) Preferably the gangliosides include GM_3 and GD_3. (p. 2 paragraph 0033) This composition can be used in a method of

treating an infection, for example *H. pylori* or *C. difficile*, or alternately irritable bowel syndrome or an arthritic condition. (p. 3 paragraphs 0042-0045) This composition is inherently considered to be a supplemented liquid or food as it comprises milk, a liquid food, supplemented with additional ganglioside. Furthermore, it is considered to be an infant food as it is suitable for administration to infants. Finally, a process of administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore Williams et al. anticipates the claimed invention.

Claims 2-4, 8, 9, 11-13, 17, 19, and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Berger et al. (US pre-grant publication 2005/0107311, cited in PTO-892)

Berger et al. discloses gangliosides obtained from buffalo milk which mediate anti-inflammatory effects. (p. 1 paragraphs 0018-0019) Gangliosides present include

GM3 and GD3. (p. 3 paragraph 0066) One specific type of buffalo milk (Pakistan buffalo mature milk) is analyzed and shown to have predominantly (over 50%) ganglioside GD3. (figure 1 in the drawings, also p. 2 paragraph 0031) This composition is a nutritionally complete consumable product, and therefore is a supplemented food. (p. 2 paragraph 0050) It can also be used in infant formulas. (p. 2 paragraph 0028) Finally, a process of administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore Berger et al. anticipates the claimed invention.

Claims 2-4, 9-13, 17, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroten. (PCT international publication WO96/058444, reference included with PTO-1449, machine translation included with PTO-892)

Schroten discloses gangliosides that are useful for treating allergies, particularly in infants and small children. (abstract, p. 2 lines 6-9) The gangliosides are added to a

food formula resulting in a supplemented food. (p. 2 lines 23-34) A preferred embodiment contains 1 mg of GM3, 30 mg of GD3, and 15 mg of GTb1. (p. 4 lines 26-28) This composition therefore comprises over 50% of GD3. Finally, a process of administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore Schroten anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US pre-grant publication 2004/0047856, cited in PTO-892)

The disclosure of Williams et al. is discussed above. Williams et al. does not disclose a method wherein the composition comprises the specific amounts of GD3 and GM3 recited in instant claims 4-7 and 19-22.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods of Williams et al. using the specific amounts of GM3 and GD3 found in claims 4-7 and 19-22. One of ordinary skill in the art would have been motivated to optimize the amounts of these critical ingredients in the therapeutic composition in order to determine the optimal amounts to use to get the desired therapeutic effect. One of ordinary skill in the art would have reasonably expected success because routine optimization of the amounts of ingredients in a prior art composition is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 4-7 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US pre-grant publication 2005/0107311, cited in PTO-892)

The disclosure of Berger et al. is discussed above. Berger et al. does not disclose a method wherein the composition comprises the specific amounts of GD3 and GM3 recited in instant claims 4-7 and 19-22.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods of Berger et al. using the specific amounts of GM3 and GD3 found in claims 4-7 and 19-22. One of ordinary skill in the art would have been motivated to optimize the amounts of these critical ingredients in the therapeutic

composition in order to determine the optimal amounts to use to get the desired therapeutic effect. One of ordinary skill in the art would have reasonably expected success because routine optimization of the amounts of ingredients in a prior art composition is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4, 6-8, 11-13, 17, 19, and 21-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6998392. (Cited in PTO-892, herein referred to as '392) Although the conflicting claims are not identical, they are not patentably distinct from each other

because claims 1-5 of '392 anticipate the claimed invention. Specifically, claim 1 of '392 is drawn to a method comprising administering a ganglioside to a subject. Admnistering a ganglioside inherently will mediate inflammation and lower serum cholesterol. Claim 2 indicates that the ganglioside contains GD3 and/or GM3, and clam 5 recites a compostion falling within the amounts of GD3 and GM3 recited in instant claims 4, 6, 7, 19, 21, and 22. Claims 3 and 4 require that the composition be a supplemented liquid or food, including an infant formula, anticipating instant claims 11, 12, 23, and 24. Therefore '392 anticipates the claimed invention.

Claims 2, 3, 8-13, 17, and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-17 of copending Application No. 11/622858. (Published as 2007/0173480, cited in PTO-892) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 9-17 of '858 anticipate the claimed invention. Specifically, claim 9 of '858 is drawn to a method of treating an inflammatory bowel disorder by administering a ganglioside and claim 16 is drawn to a similar method of lowering blood cholesterol. Claims 13 and 17 of '858 indicate that the ganglioside can include GD3 and/or GM3. Claims 14 and 15 of '858 specify that the composition is a supplemented liquid or food, or an infant formula. Therefore '858 anticipates the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
10/29/2008

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623